

Hydrocolloid Adhesive Compositions

This Apph claims benefit of Provisional No. 60/106,799 filed Nov. 3, 1998.

BACKGROUND OF THE INVENTION

The present invention relates to pressure sensitive adhesive compositions and more particularly to pressure sensitive hydrocolloid adhesive compositions suited for use in ostomy, wound and incontinence care.

The compositions of this invention can be used for example to hold ostomy or incontinence devices onto the body of the user or to hold wound dressings in position for treating skin ailments or as the wound dressing itself.

Various hydrocolloid adhesive compositions suitable for medical uses are disclosed in the patent literature, e.g., U.S. Patent Nos. 3,339,549 (Chen); 4,192,785 (Chen, et al.); 4,166,051 (Cilento, et al.); 4,393,080 (Pawelchak, et al.); 3,612,053 (Pratt, et al.); 4,231,369 (Sorensen, et al.); 3,908,658 (Marsan); 4,367,732 (Poulsen, et al.); 4,378,018 (Alexander, et al.); and 4,393,150 (Krones).

Hydrocolloid adhesives are composed of powdered hydrocolloids dispersed in an elastomeric polymer matrix. They have been found to make excellent pressure sensitive adhesives for attachment of devices to the skin. Useful hydrocolloid adhesives depend on their initial tack, cohesive strength, and absorbency to achieve wearing times on skin of up to 10 days or longer. It is also required that components of hydrocolloid adhesives be cost effective, easy to process, and compatible with other device components.

OBJECT OF THE INVENTION

It is an object of the present invention to provide a biocompatible hydrocolloid adhesive composition simultaneously having preferred probe tack, tensile strength and saline absorbency as provided in Table I.

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Table 1

Characteristic	Usefulness Range	Preferred Range	
Probe Tack	About 300 - 750 grams, force	About 500-650 grams, force	
Tensile Strength	About 500 - 3500 grams/cm ²	About 1500 - 2500 g/cm ² extruded	About 500- 1500 non-extruded
Saline Absorbency	About 500 - 5000 g/m ² /day	About 2000 - 3500 g/m ² /d extruded	About 1500-2500 non-extruded

It is also an object of the present invention to provide a biocompatible adhesive that is easy to process, cost efficient, durable and that doesn't swell excessively when hydrated.

It is an object to achieve with the present invention probe tack values above about 300 grams, force, as this value has been found to be desirable for attaining a strong initial bond to the skin. Improved bonds are generally obtained with increased tack, though too strong a bond may damage skin upon removal

It is also an objective of the present invention to achieve acceptable shear strength and peel properties. It has been determined that tensile strengths of about 500 - 3500 g/square centimeter are desirable. It is also recognized, however, that decreased flexibility or reduced adhesion may result if cohesive strength is excessive.

DESCRIPTION OF THE INVENTION

The adhesive compositions of the present invention utilize a poly(ethylene-propylene) rubber (EPR) having a broad molecular weight, amorphous structure and an ethylene content of 50% or less. The EPR is also a random copolymer and easy to process. The preferred EPR is Vistalon 404, Exxon Chemical Co. Low molecular weight species in the EPR favor bond formation while higher molecular weight species enhance cohesive and peel strength. A compatible tackifying resin for this elastomer preferred for optimum tackification is a low molecular weight, highly hydrogenated polyvinylcyclohexane. Commercially available examples are Regalrez® 1085 or Regalrez® 1094. (Hercules, Inc.). It is further preferred that the polyvinylcyclohexane have a softening point below body temperature and most preferably below

room temperature such that it may further improve the wetting of skin by the elastomeric component. A commercially available example is Regalrez® 1018 (Hercules, Inc.). In particular, the use of low softening point resin allows for increasing the concentration of tackifier by a corresponding reduction in the concentration of plasticizing components. Both factors favorably influence adhesion, while retaining flexibility that may be lost when resins of higher softening point are employed. Adhesion is easily measured by using a task test to determine the bond forming capability.

Because hydrocolloid adhesives are composed of an elastomeric phase and a hydrocolloid phase, proper optimization of the adhesive formulation requires simultaneous optimization of the individual phases. While some interaction does occur between phases, the elastomeric phase is primarily responsible for the adhesive and cohesive strength properties, and the hydrocolloid phase is primarily responsible for the overall moisture handling and moisture interaction characteristics of the formulation. Adhesion and cohesion typically represent a balance of competing behaviors, and strong elastomers may not yield very effective adhesives. Moisture handling is more than just absorption, per se, but must be thought of in terms of absorption rate, absorption capacity, and the properties of the hydrated material. The hydrocolloid phase is key in determining these characteristics.

The ability of the adhesive to form a bond to the skin is directly related to the probe tack of the adhesive. Tack is generated by the action of tackifying resins to enhance wetting of the skin by the elastomeric components of the formulation. Modification of elastomers by tackifiers enables elastomers to form bonds while retaining their cohesiveness and contribute strength to the overall formulation. Compatibility of the tackifier with the elastomer is believed to be a key factor in tackifier effectiveness, as is the presence of low molecular weight species in the elastomer. Typically, the elastomer is blended with a styrenic block copolymer for optimum cohesive strength.

In order to attain adhesion to the skin for more than 1 or 2 days, it is necessary that the adhesive absorb fluid at a rate greater than or equal to the rate of transepidermal water loss (TEWL), approximately 7-10 g/square meter per hour on average. The actual absorption rate required to maintain skin adhesion can in practice be somewhat greater than this value as a

function of weather, physical activity, etc. To obtain the minimum absorption capacity, this absorption rate should be multiplied over the wearing time.

Absorption by the adhesive is necessary to effectively manage perspiration from the skin. Without this capability, the adhesive would fail after short wearing times, and skin condition would be adversely affected. However, absorption also causes degradation of the adhesive component resulting from hydration and chemical attack by stomal discharge. This degradation occurs because the absorbent hydrocolloids act regardless of the source of the fluid absorbed, either perspiration or stoma effluent. Therefore, limiting absorption to the minimum necessary to manage perspiration will limit how stoma fluid will impact dressing integrity.

Denture adhesives are an example of water activated adhesives. Typically, sodium carboxy-methyl cellulose (NaCMC) is used as a component of these formulations. A blend of NaCMC grades is used to achieve desired properties. Differences between grades are defined by the degree of substitution (DS) of carboxymethyl groups onto the anhydroglucose repeat units of the cellulose chain. Higher DS grades (>1.0) are used to impart a high rate of absorption, while lower to moderate DS grades (<1.0) are included for their long term cohesiveness. One further requirement of the formulation is that its response to moisture must not compromise the performance of the device for which the adhesive was intended. As hydrocolloid adhesives absorb moisture they begin to swell. The hydrating hydrocolloid powders transform the rubbery elastomer phase into a more gelatinous composition that appears to grow. Typically this growth occurs in the direction of a free surface. For wound dressings the growth is into the wound. For ostomy skin barriers the growth is toward the stoma, and is called turtlenecking for its resemblance to the collar on a turtleneck sweater.

In some cases turtlenecking is desirable, as it has been reported to provide an effective seal around the stoma itself and prevents leakage of stomal effluent and undermining of the skin barrier. However, excessive amounts of turtlenecking can have the opposite effect, causing effluent to be diverted from the pouch and against the skin. Excessive turtlenecking in hydrocolloid adhesives can be avoided by limiting elongation of the elastomeric phase during hydration. Key factors in attaining acceptable turtlenecking are the choice of elastomer, the

balance of absorption rate and capacity within the limits described above, the balance of cohesive and adhesive properties in the elastomer phase.

In contrast to denture adhesives, it has been discovered that use of higher DS CMC grades in combination with low to moderate DS grades reduces the rate of moisture absorption in hydrocolloid adhesives. In other words, as the average degree of substitution of the CMC in the formulation increases, the absorption rate of the hydrocolloid adhesive decreases. Further, overall absorption capacity increases. As a result, longer wearing times are possible because the influence of stomal effluent on adhesive integrity is reduced, though the film forming and water activated bonding capabilities of CMC are retained. Additionally, turtlenecking characteristics are favorably impacted.

Although it is possible to lower the absorption rate of the formulation by using different hydrocolloids having a weaker affinity for water, the impact on overall adhesive properties is not as favorable as with the use of higher DS CMC. Examples 34 and 35 below show how use of pregelatinized starch, a low absorbing hydrocolloid, reduces the absorption rate of the formulation. However, in contrast with the performance of high DS CMC, the overall absorption capacity of the adhesive is not increased. Further, the water activated bonding power of hydrated starch to human skin is not believed to be as effective as either pectin or especially CMC. Therefore, addition of a minor amount of starch, or other low absorbing hydrocolloids, may expand the useful range of this invention to the extent that the effectiveness of the preferred hydrocolloids in extending wear time is not compromised.

Addition of a small amount of a powdered cellulose, which is not a hydrocolloid but a water swellable powder, is also useful for reducing moisture absorption while still being of similar composition to NaCMC. A further benefit of adding powdered cellulose is that it improves cohesive strength of the overall formulation.

As a result of the fact that the EPR is can be readily blended with the other formulation components, a variety of conventional compounding processes are believed to be suitable for obtaining a homogeneous mixture. Potential mixing processes would include solvent blending,

continuous or semi-continuous compounding, calendering or milling, and internal or external mixers. The preferred mixing process utilizes a high intensity batch mixer, which has been heated to between 250 and 330°F. The process proceeds by alternating additions of rubber or block copolymer with any of the powders and one of the low molecular weight components, which are mixed in groups until homogeneous. The entire process proceeds for as long as about 90 minutes or more. The low molecular weight components include any of the tackifiers and the plasticizer. The plasticizer used should be a low molecular weight polymer appropriately chosen to reduce the modulus of the formulation, promote flexibility and conformability of the adhesive, and be suitable for contact with the skin or mucosal tissue. Preferably petrolatum may be used.

Formulated adhesive mass may then be formed by any of various means into smooth sheets. The preferred forming methods are extrusion or compression. A useful thickness range for the adhesive is believed to be in the range between 0.005 inch and 0.25 inch. This adhesive sheet may be laminated with a wide variety of films, foams, non-woven or other fabrics, etc. and also to paper, some of which may have been coated with release agents to promote removal. The adhesive sheet may be cut into useful sizes, shapes and dimensions including discs, profiles, contours or other constructions of adhesive articles. Laminates may be added readily to the adhesive when it is maintained at elevated temperature. Preferred methods of lamination include a roll based lamination station or a compression type process. Cutting may be accomplished using several methods, the preferred ones being a rotary cutting die or a platen type cutting die.

EXAMPLES

Table 2 provides a listing of 25 hydrocolloid adhesives pursuant to the present invention. Each of these compositions are blended to produce compositions with the characteristics listed in Table 2A within the usefulness ranges of Table 1.

Additional examples showing the utility of the invention are shown in Table 6.

Examples of the trade names for components of the compositions are the following:

ethylene propylene rubber – Vistalon 404, Exxon Chemical Co.;

styrenic block copolymer – Kraton D1107, Shell Chemical Co.;

tackifier (solid) – Piccotac 95, Hercules, Inc.;

tackifier (liquid) – Regalrez 1018, Hercules, Inc.;

NaCMC - Sodium Carboxymethyle cellulose FCC grade with

DS7 = degree of substitution = 0.7

DS12 = degree of substitution = 1.2

pectin - Pectin, USP 100;

powdered cellulose, FCC - Solka Floc 200 FCC, Fiber Sales & Development Corp.

Antioxidant - Irganox 1010, Ciba Geigy Corp.;

Plasticizer - white petrolatum, USP;

Cyclo-aliphatic tackifying resin - Relarez 1094, Hercules, Inc.;

Hydrogenated rosin ester - Pentalyn H., Hercules, Inc.;

Pregelatinized starch - Prejel PA5, Avebe, Inc.

Examples 1-4 and 17-20 of Tables 2 and 2A demonstrate acceptable performance within the usefulness ranges of Table 1. These examples represent a base adhesive which has no liquid tackifier, high DS DMC, or powdered cellulose but still achieves useful properties. Improvements to probe tack resulting from the use of low softening point tackifier are shown in Table 3. The effectiveness of high degree of substitution sodium carboxymethyl cellulose to reduce absorption is shown in Table 5. The ability of powdered cellulose to reduce absorption and increase strength is demonstrated in Table 4.

Measurements of probe tack were based on the method described in ASTM D2979 using an inverted probe machine. In this test, conducted at room temperature, the dwell time was 1 second, and the approach speed was 1 cm/second. Tensile measurements were based on ASTM test method D412 with the crosshead speed set to 200 mm/minute using a dumb bell shaped test specimen. The peak tensile strength is reported. Absorbency measurements were conducted based on the British Pharmacopoeia method wherein a flat adhesive specimen of known weight and area is exposed to 0.9% saline solution. The exposed adhesive is incubated at body temperature for 24 hours and re-weighed. The weight difference per area is reported.

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Table 2

Example	Ethylene-Propylene Rubber	Styrenic Block Copolymer	Tackifying Resin	Anti-oxidant	NaCMC DS7	Pectin	Low Softening Point Tackifier	Plasticizer	NaCMC DS12	Powdered Cellulose
1	6.0%	13.0%	28.0%	0.5%	33.0%	10.0%		9.5%		
2	2.0%	10.0%	33.0%	0.5%	27.0%	20.0%		7.5%		
3	10.0%	16.0%	24.0%	0.5%	32.5%	5.0%		12.0%		
4	7.0%	10.5%	28.0%	0.5%	26.0%	20.0%		8.0%		
5	6.0%	13.0%	30.0%	0.5%	35.0%	7.0%		8.5%		
6	6.0%	13.0%	28.0%	0.5%	35.0%	7.0%	2.0%	8.5%		
7	6.0%	13.0%	25.0%	0.5%	35.0%	7.0%	5.0%	8.5%		
8	6.0%	13.0%	28.0%	0.5%	35.0%	7.0%	5.0%	5.5%		
9	6.0%	13.0%	28.0%	0.5%	30.0%	7.0%	5.0%	5.5%	5.0%	
10	6.0%	13.0%	28.0%	0.5%	20.0%	7.0%	5.5%	5.5%	15.0%	
11	6.0%	13.0%	28.0%	0.5%	10.0%	7.0%	5.5%	5.5%	25.0%	
12	6.0%	13.0%	25.0%	0.5%	15.0%	15.0%	5.5%	5.0%	15.0%	
13	5.0%	12.5%	25.0%	0.5%	28.0%	15.0%	2.0%	7.0%	5.0%	3.0%
14	5.0%	12.5%	25.0%	0.5%	25.0%	15.0%	2.0%	7.0%	5.0%	6.0%
15	5.0%	12.5%	25.0%	0.5%	22.0%	15.0%	2.0%	7.0%	5.0%	2.0%
16	5.0%	12.5%	28.0%	0.5%	20.0%	15.0%	2.0%	7.0%	8.0%	
17	5.0%	12.5%	28.0%	0.5%	30.0%	15.0%		9.0%		
18	2.0%	15.5%	28.0%	0.5%	30.0%	15.0%		9.0%		
19	8.0%	9.5%	28.0%	0.5%	30.0%	15.0%		9.0%		
20	5.0%	12.5%	28.0%	0.5%	30.0%	15.0%		9.0%		
21	5.0%	12.5%	28.0%	0.5%	30.0%	15.0%	3.0%	6.0%		
22	2.0%	15.5%	28.0%	0.5%	30.0%	15.0%	6.0%	3.0%		
23	8.0%	9.5%	25.0%	0.5%	30.0%	15.0%	3.0%	9.0%		
24	8.0%	9.5%	25.0%	0.5%	30.0%	15.0%	6.0%	6.0%		
25	8.0%	9.5%	28.0%	0.5%	20.0%	15.0%	3.0%	6.0%	10.0%	

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Section 1B Table 2A

Table 2A

Example	Probe Tack g tack force	Tensile Strength g/cm ² (non-extruded)	24 Hr Saline Absorption g/sq.m/24 hr (non-extruded)
1	432	852	1937
2	411	2966	3459
3	470	860	1439
4	418	1465	2936
5	559	1690	2111
6	481	1451	2479
7	517	1637	2947
8	615	1690	3507
9	586	1587	2859
10	418	1574	2113
11	438	2065	1538
12	477	1757	2257
13	572	1032	3590
14	449	1919	3237
15	425	1830	2446
16	599	1312	1869
17	508	662	2200
18	426	1538	2705
19	529	824	3249
20	491	1205	2209
21	531	998	2843
22	420	2183	2861
23	394	587	2326
24	450	632	3107
25	597	873	2426

Examples Showing Improvement in Tack Using Low Softening Point Tackifier

Example	Ethylene-Propylene Rubber	Styrenic Block Copolymer	Tackifying Resin	Anti-oxidant	NaCMC Low DS	Pectin	Low Softening Point Tackifier	Plasticizer	NaCMC High DS	Powdered Cellulose	Probe Tack
	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	g tack force
1	6.0%	13.0%	28.0%	0.5%	33.0%	10.0%		9.5%			432
2	2.0%	10.0%	33.0%	0.5%	27.0%	20.0%		7.5%			411
3	10.0%	16.0%	24.0%	0.5%	32.5%	5.0%		12.0%			470
4	7.0%	10.5%	28.0%	0.5%	26.0%	20.0%		8.0%			418
6	6.0%	13.0%	28.0%	0.5%	35.0%	7.0%	2.0%	8.5%			481
7	6.0%	13.0%	25.0%	0.5%	35.0%	7.0%	5.0%	8.5%			517
8	6.0%	13.0%	28.0%	0.5%	35.0%	7.0%	5.0%	5.5%			615
21	5.0%	12.5%	28.0%	0.5%	30.0%	15.0%	3.0%	6.0%			531
25	8.0%	9.5%	28.0%	0.5%	20.0%	15.0%	3.0%	6.0%	10.0%		597

Table 4

Examples Showing Improvement in Tensile Strength Using Powdered Cellulose

Example	Ethylene-Propylene Rubber	Styrenic Block Copolymer	Tackifying Resin	Anti-oxidant	NaCMC Low DS	Pectin	Low Softening Point Tackifier	Plasticizer	NaCMC High DS	Powdered Cellulose	Tensile Strength
	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	g/cm ²
13	5.0%	12.5%	25.0%	0.5%	28.0%	15.0%	2.0%	7.0%	5.0%		1032
14	5.0%	12.5%	25.0%	0.5%	25.0%	15.0%	2.0%	7.0%	5.0%	3.0%	1919
15	5.0%	12.5%	25.0%	0.5%	22.0%	15.0%	2.0%	7.0%	5.0%	6.0%	1830
16	5.0%	12.5%	28.0%	0.5%	20.0%	15.0%	2.0%	7.0%	8.0%	2.0%	1312

Table 5

Examples Showing Reduced Absorption Using High Degree of Substitution CMC

Example	Ethylene-Propylene Rubber	Styrenic Block Copolymer	Tackifying Resin	Anti-oxidant	NaCMC Low DS	Pectin	Low Softening Point Tackifier	Plasticizer	NaCMC High DS	Powdered Cellulose	24 Hr Saline Absorption
	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	% w/w	g/sq.m/24 hr
8	6.0%	13.0%	28.0%	0.5%	35.0%	7.0%	5.0%	5.5%			3507
9	6.0%	13.0%	28.0%	0.5%	30.0%	7.0%	5.0%	5.5%	5.0%		2859
10	6.0%	13.0%	28.0%	0.5%	20.0%	7.0%	5.5%	5.5%	15.0%		2113
11	6.0%	13.0%	28.0%	0.5%	10.0%	7.0%	5.5%	5.5%	25.0%		1538
12	6.0%	13.0%	25.0%	0.5%	15.0%	15.0%	5.5%	5.0%	15.0%		2257
25	8.0%	9.5%	28.0%	0.5%	20.0%	15.0%	3.0%	6.0%	10.0%		2426

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Table 6: Additional Formulation Examples Demonstrating the Utility of the Invention

Example	Ethyl ene- Propy lene Rubber	Styrenic Block Copolymer	Tackifying Resin	Anti- oxidant	NaCMC DS7	Pectin	Low Softening Point Tackifier	Plasticizer	NaCMC DS12	Powdered Cellulose	Hydrogenated Rosin Ester	Cyclo-aliphatic tackifying Resin	Terpene Resin	Pregelatin- ized Starch
26	20	2	25	0.5	14	14	5.5	5	14					
27	5	10	30.5	0.5	15.5	30.5		8						
28	5	10	25	0.5	33	17		9.5						
29	5	10	25	0.5	35	12.5		12						
30	5	12.5		0.5	20	15	2	7	8	2	28			
31	13	6		0.5	15	15	5.5	5	15			25		
32	5	12.5	14	0.5	20	15	2	7	8	2		14		15
33	5	12.5	28	0.5	15	15		9						20
34	5	12.5	29	0.5	10	15		8						

Example	Probe Tack		Tensile Strength		24 Hr Saline Absorption	
	g tack force		g/cm ²		g/sq. m/24 hr	
26	504		1714		4788	
27	757		1706		2688	
28	467		---		6006	
29	370		4778		---	
30	644		975		6669	
31	470		1318		3845	
32	409		1673		1985	
33*	456		1849		2772	
34*	525		2076		2790	

* Data for examples 33 and 34 is for extruded product.